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Al-Ali

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(54) **CYANOTIC INFANT SENSOR**

(71) Applicant: **MASIMO CORPORATION**, Irvine, CA (US)

(72) Inventor: **Ammar Al-Ali**, San Juan Capistrano, CA (US)

(73) Assignee: **MASIMO CORPORATION**, Irvine, CA (US)

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Related U.S. Application Data

(63) Continuation of application No. 13/100,145, filed on May 3, 2011, now Pat. No. 8,682,407, which is a continuation of application No. 11/171,632, filed on Jun. 30, 2005, now Pat. No. 7,937,128.

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(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/14551*** (2013.01); ***A61B 5/0059*** (2013.01); ***A61B 5/14552*** (2013.01); ***A61B 5/7271*** (2013.01); *A61B 2503/04* (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/1455; A61B 5/14551; A61B 5/14552; A61B 5/72; A61B 5/7271
See application file for complete search history.

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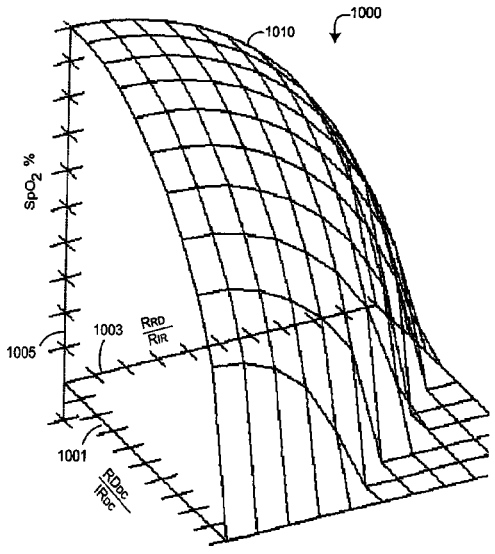
Primary Examiner — Eric Winakur
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

A pulse oximetry sensor comprises emitters configured to transmit light having a plurality of wavelengths into a fleshy medium. A detector is responsive to the emitted light after absorption by constituents of pulsatile blood flowing within the medium so as to generate intensity signals. A sensor head has a light absorbing surface adapted to be disposed proximate the medium. The emitters and the detector are disposed proximate the sensor head. A detector window is defined by the sensor head and configured so as to limit the field-of-view of the detector.

20 Claims, 7 Drawing Sheets



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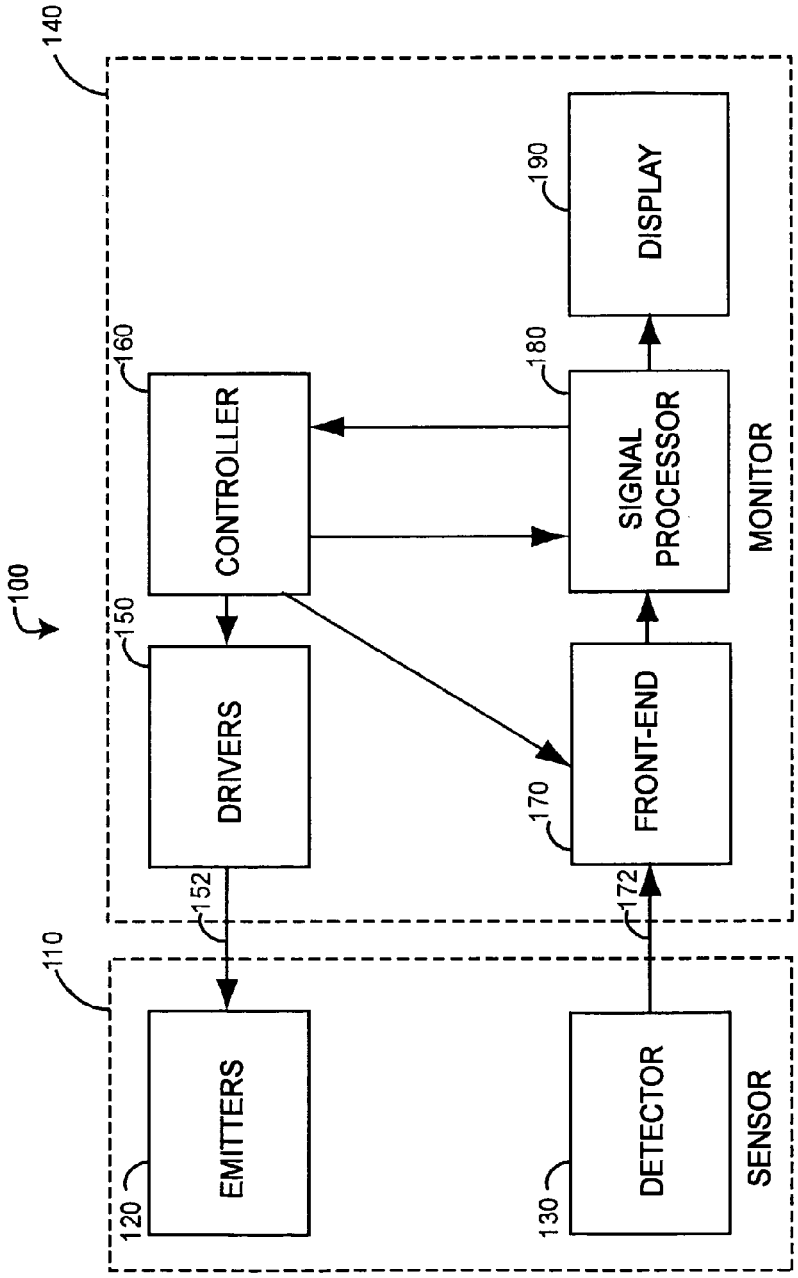

FIG. 1 (Prior Art)

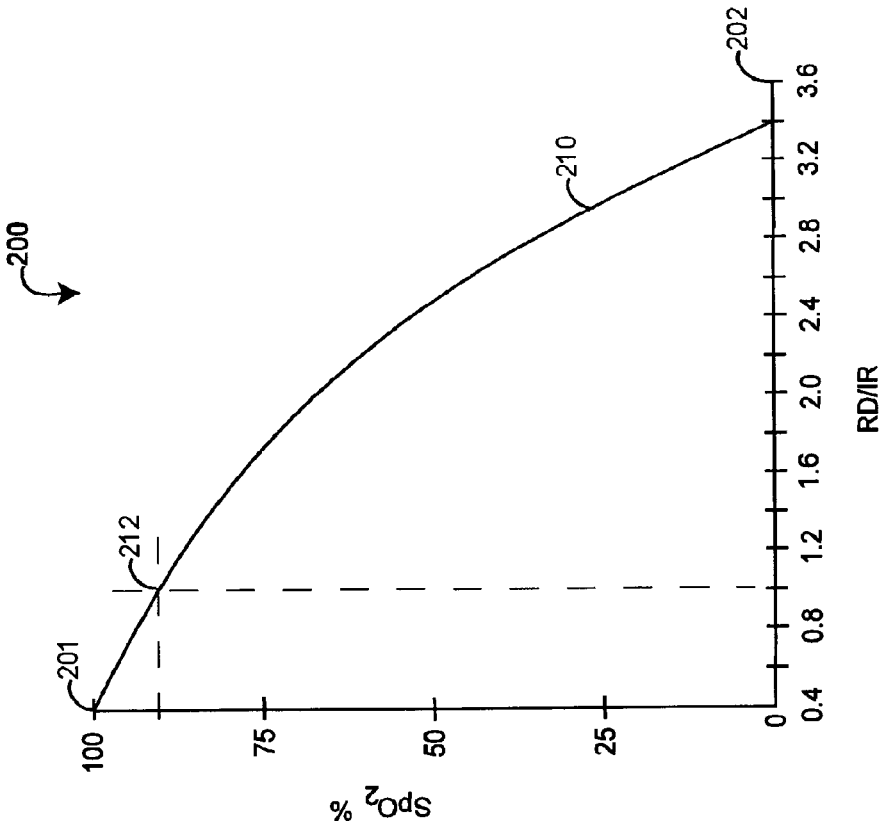

FIG. 2 (Prior Art)

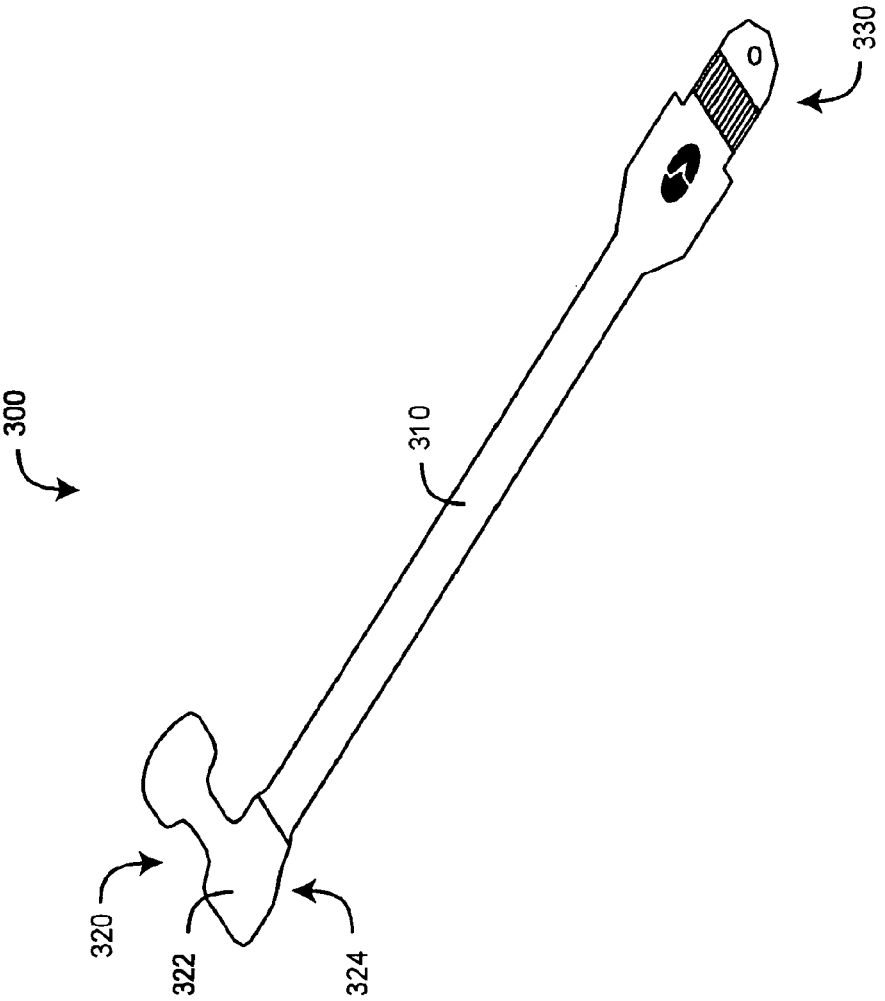

FIG. 3A

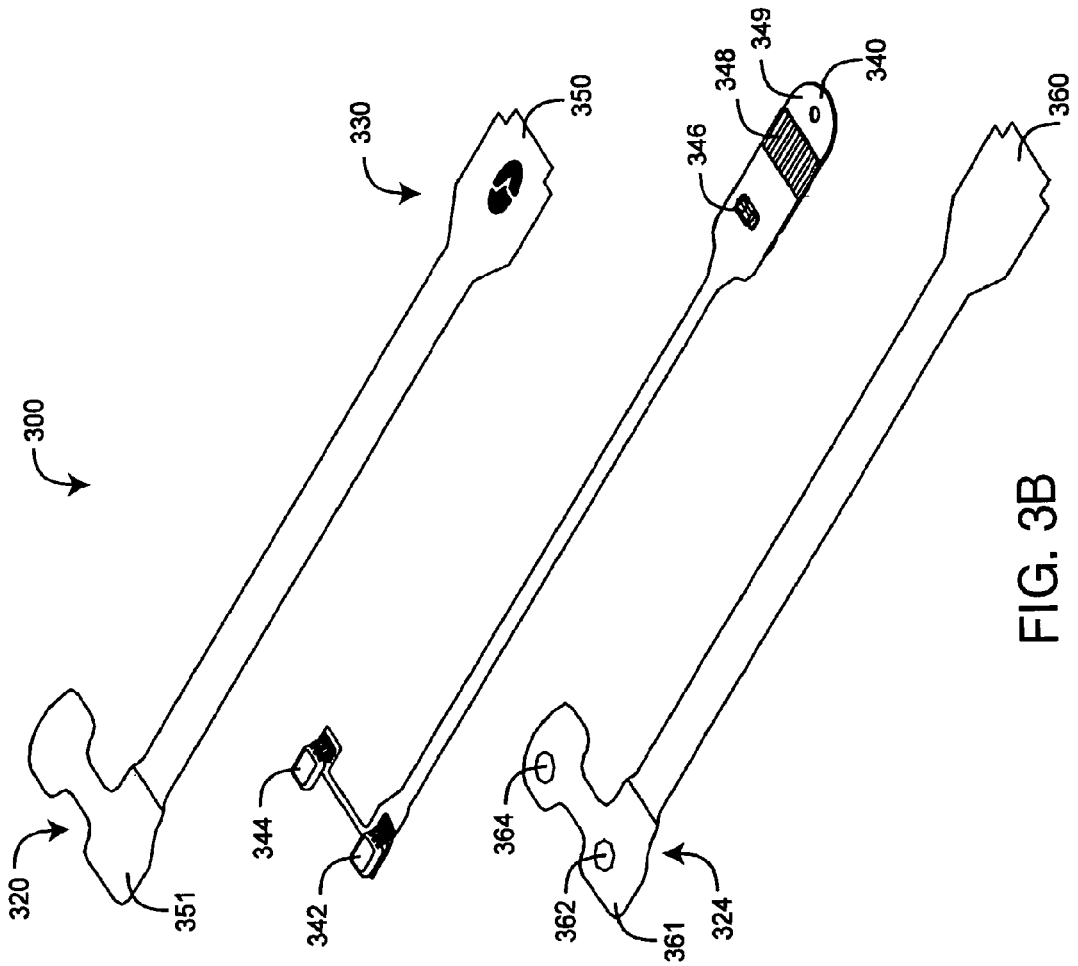

FIG. 3B

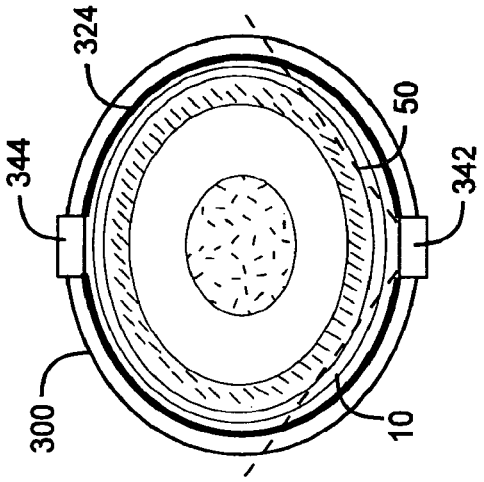

FIG. 6

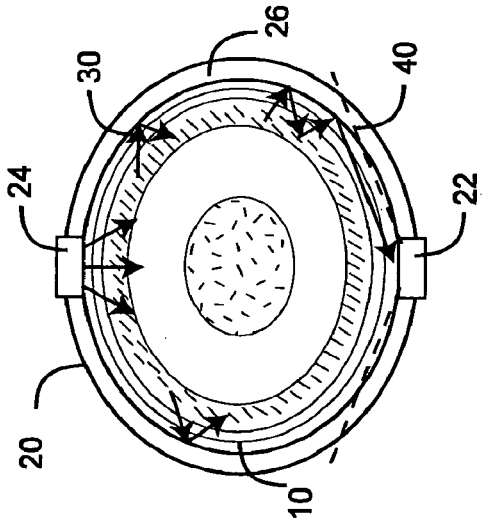

FIG. 5 (Prior Art)

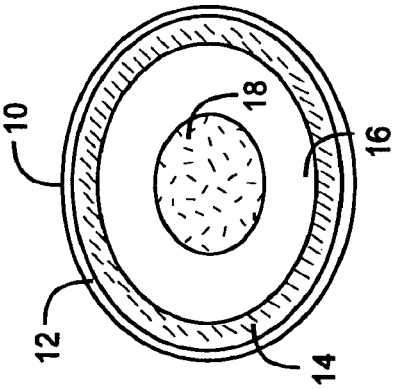

FIG. 4

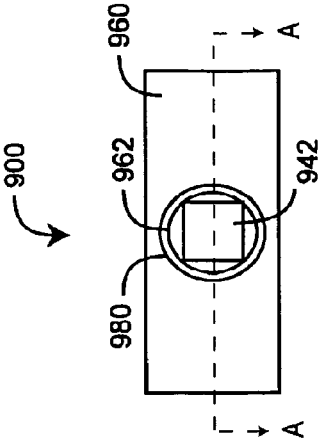

FIG. 9A

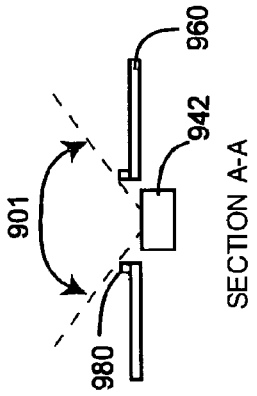

FIG. 9B

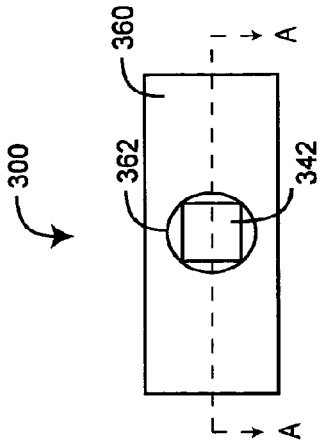

FIG. 8A

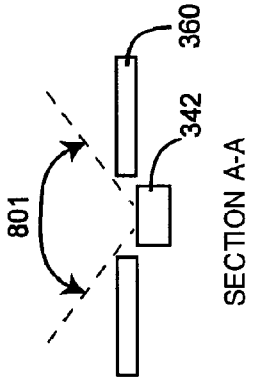

FIG. 8B

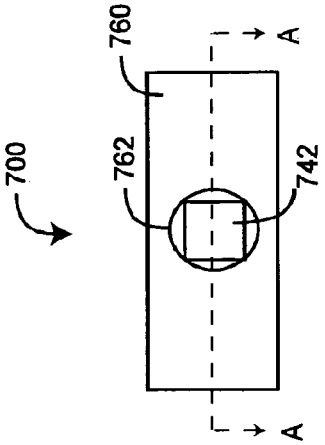

FIG. 7A (Prior Art)

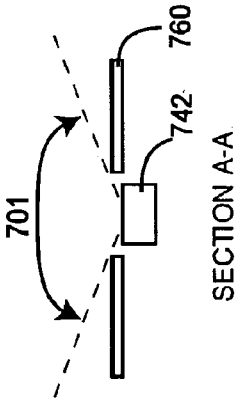

FIG. 7B (Prior Art)

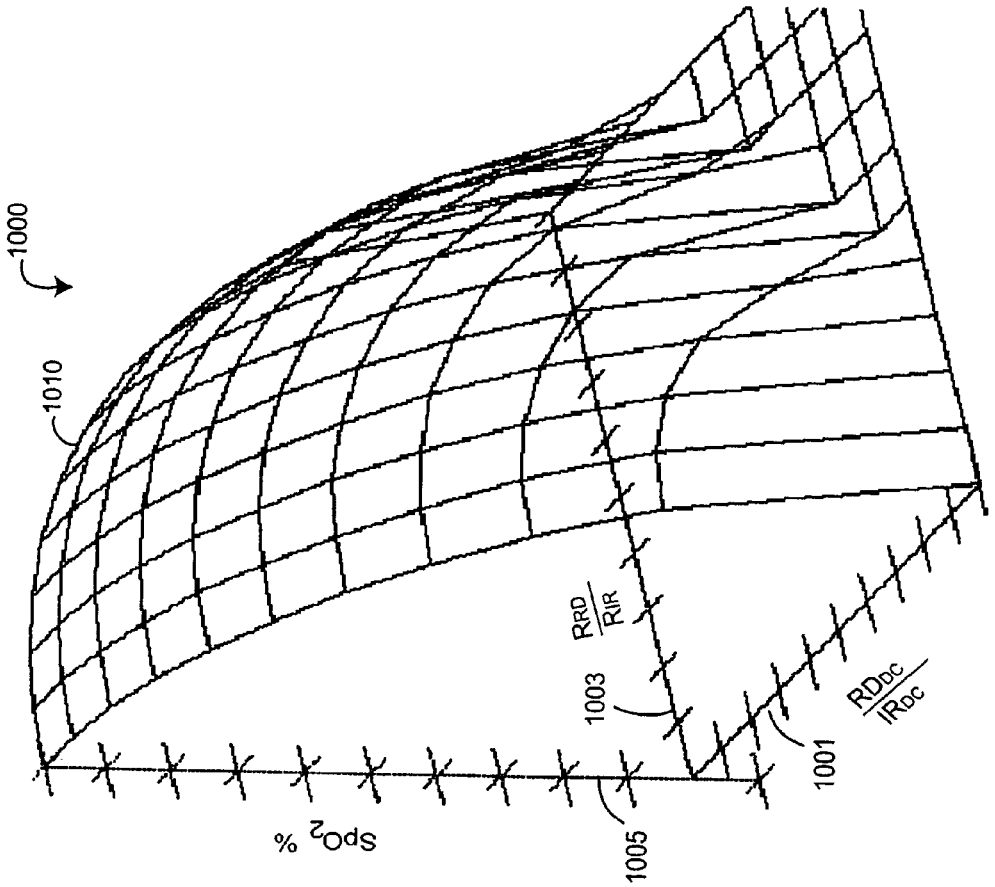

FIG. 10

CYANOTIC INFANT SENSOR

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims priority benefit under 35 U.S.C. §120 to, and is a continuation of U.S. patent application Ser. No. 13/100,145, filed May 3, 2011 entitled "Cyanotic Infant Sensor," now U.S. Pat. No. 8,682,407, which is a continuation of U.S. patent application Ser. No. 11/171,632, filed Jun. 30, 2005 entitled "Cyanotic Infant Sensor," now U.S. Pat. No. 7,937,128, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/586,821, filed Jul. 9, 2004, entitled "Cyanotic Infant Sensor." The present application also incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

Cyanosis is a congenital condition in which blood pumped to the body contains less than normal amounts of oxygen, resulting in a blue discoloration of the skin. The most common cyanotic condition is tetralogy of Fallot, which is characterized by an abnormal opening, or ventricular septal defect, that allows blood to pass from the right ventricle to the left ventricle without going through the lungs; a narrowing, or stenosis, proximate the pulmonary valve, which partially blocks the flow of blood from the right side of the heart to the lungs; a right ventricle that is abnormally muscular; and an aorta that lies directly over the ventricular septal defect. Another cyanotic condition is tricuspid atresia, characterized by a lack of a tricuspid valve and resulting in a lack of blood flow from the right atrium to the right ventricle. Yet another cyanotic condition is transposition of the great arteries, i.e. the aorta originates from the right ventricle, and the pulmonary artery originates from the left ventricle. Hence, most of the blood returning to the heart from the body is pumped back out without first going to the lungs, and most of the blood returning from the lungs goes back to the lungs.

Pulse oximetry is a useful tool for diagnosing and evaluating cyanotic conditions. A pulse oximeter performs a spectral analysis of the pulsatile component of arterial blood so as to measure oxygen saturation, the relative concentration of oxygenated hemoglobin, along with pulse rate. FIG. **1** illustrates a pulse oximetry system **100** having a sensor **110** and a monitor **140**. The sensor **110** has emitters **120** and a detector **130** and is attached to a patient at a selected fleshy tissue site, such as a thumb or toe. The emitters **120** project light through the blood vessels and capillaries of the tissue site. The detector **130** is positioned so as to detect the emitted light as it emerges from the tissue site. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

Also shown in FIG. **1**, the monitor **140** has drivers **150**, a controller **160**, a front-end **170**, a signal processor **180**, a display **190**. The drivers **150** alternately activate the emitters **120** as determined by the controller **160**. The front-end **170** conditions and digitizes the resulting current generated by the detector **130**, which is proportional to the intensity of the detected light. The signal processor **180** inputs the conditioned detector signal and determines oxygen saturation, as described below, along with pulse rate. The display **190** provides a numerical readout of a patient's oxygen saturation and pulse rate. A pulse oximetry monitor is described in

U.S. Pat. No. 5,482,036 entitled "Signal Processing Apparatus and Method," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein.

SUMMARY OF THE INVENTION

The Beer-Lambert law provides a simple model that describes a tissue site response to pulse oximetry measurements. The Beer-Lambert law states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the mean pathlength, mpl_λ, the intensity of the incident light, $I_{0,\lambda}$, and the extinction coefficient, $\epsilon_{i,\lambda}$, at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-mpl_\lambda \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \tag{2}$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. For conventional pulse oximetry, it is assumed that there are only two significant absorbers, oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb). Thus, two discrete wavelengths are required to solve EQS. 1-2, e.g. red (RD) and infrared (IR).

FIG. **2** shows a graph **200** depicting the relationship between RD/IR **202** and oxygen saturation (SpO_2) **201**, where RD/IR denotes the ratio of the DC normalized, AC detector responses to red and infrared wavelengths, as is well-known in the art and sometimes referred to as the "ratio-of-ratios." This relationship can be approximated from Beer-Lambert's Law, described above. However, it is most accurately determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation. The result can be depicted as a curve **210**, with measured values of RD/IR shown on an x-axis **202** and corresponding saturation values shown on a y-axis **201**. In a pulse oximeter device, this empirical relationship can be stored in a read-only memory (ROM) for use as a look-up table so that SpO_2 can be directly read-out from an input RD/IR measurement. For example, an RD/IR value of 1.0 corresponding to a point **212** on the calibration curve **210** indicates a resulting SpO_2 value of approximately 85%.

Accurate and consistent pulse oximetry measurements on cyanotic infants have been difficult to obtain. An assumption inherent in the calibration curve **210** (FIG. **2**) is that the mean pathlength ratio for RD and IR is constant across the patient population. That is:

$$mpl_{RD}/mpl_{IR}=C \tag{3}$$

However, EQ. 3 may not be valid when cyanotic infants are included in that population. The reason may lie in what has been observed as abnormal tissue tone or lack of firmness associated with cyanotic defects, perhaps due to reduced tissue fiber. Such differences in tissue structure may alter the mean pathlength ratio as compared with normal infants. A cyanotic infant sensor addresses these problems by limiting variations in the RD over IR mean pathlength ratio and/or by providing a mean pathlength ratio measure so as to compensate for such variations. Alone or combined, these sensor

apparatus and algorithms increase the accuracy and consistency of pulse oximetry measurements for cyanotic infants.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram of a prior art pulse oximetry system;

FIG. **2** is an exemplar graph of a conventional calibration curve;

FIGS. **3**A-B are a perspective and an exploded perspective views, respectively, of a cyanotic infant sensor embodiment;

FIGS. **4-5** depict cross-sectional views of a tissue site and an attached pulse oximeter sensor, respectively;

FIG. **6** depicts a cross-sectional view of a tissue site and an attached cyanotic infant sensor;

FIGS. **7**A-B are plan and cross-sectional sensor head views of a conventional pulse oximeter sensor;

FIGS. **8**A-B and **9**A-B are plan and cross-sectional sensor head views of cyanotic infant sensor embodiments; and

FIG. **10** is an exemplar graph of a calibration surface incorporating a mean pathlength ratio measure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **3**A-B illustrate one embodiment of a cyanotic infant sensor. The sensor has a light absorbing surface, as described with respect to FIGS. **4-6**, below. The sensor also has a detector window configured to limit the detector field-of-view (FOV), as described with respect to FIGS. **7-9**, below. Advantageously, these features limit mean pathlength ratio variations that are particularly manifest in cyanotic patients.

The sensor emitters and detector are also matched so as to limit variations in the detector red over IR DC response, i.e. RD_{DC}/IR_{DC}, that are not attributed to variations in the mean pathlength ratio (EQ. 3). Such matching advantageously allows for measurement and calibration of the mean pathlength ratio, as described with respect to FIG. **10**, below. In one embodiment, cyanotic infant sensors **300** are constructed so that:

$$\lambda_{RD} \approx c_1;\ \lambda_{IR} \approx c_2 \tag{4}$$

$$I_{0,RD}/I_{0,IR} \approx c_3;\ \text{for } i_{DC}(RD),\ i_{DC}(IR) \tag{5}$$

$$RD_{DC}/IR_{DC} \approx c_4 \tag{6}$$

That is, sensors **300** are constructed from red LEDs and IR LEDs that are each matched as to wavelength (EQ. 4). The LEDs are further matched as to red over IR intensity for given DC drive currents (EQ. 5). In addition, the sensors **300** are constructed from detectors that are matched as to red over IR DC response (EQ. 6).

As shown in FIG. **3**A, the sensor **300** has a body **310** physically connecting and providing electrical communication between a sensor head **320** and a connector **330**. The sensor head **320** houses the emitters and detector and attaches to a patient tissue site. The connector mates with a patient cable so as to electrically communicate with a monitor. In one embodiment, a sensor head surface **324** is constructed of light absorbing material.

As shown in FIG. **3**B, the sensor **300** has a face tape **330**, a flex circuit **340** and a base tape **360**, with the flex circuit **340** disposed between the face tape **330** and the base tape **360**. The flex circuit **340** has a detector **342**, an emitter **344** with at least two light emitting diodes (LEDs), an information element **346**, and contacts **348** disposed on a connector tab **349**. Neonatal sensors having a detector, LEDs, an information element, contacts and connector tab are described in U.S. Pat. No. 6,256,523 entitled "Low-Noise Optical Probes," which is assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. In one embodiment, the face tape **350** and base tape **360** are constructed of Betham tape having attached polyethylene head tapes **351**, **361**. In a particular embodiment, the base head tape **361** is made of black polyethylene, and the face head tape **351** is made of white polyethylene. In one embodiment, a clear tape layer is disposed on the base head tape **361** tissue side over the detector window **362**. The base head tape **361** has a detector window **362** and an emitter window **364** each allowing light to pass through the base head tape **361**. In one embodiment, the base head tape **361** has a 4 mil thickness and the flex circuit has a 10 mil thickness. The combined 14 mil material thickness functions to limit the detector FOV, as described with respect to FIGS. **6** and **8**, below.

FIGS. **4-6** illustrate some of the pathlength control aspects of a cyanotic infant sensor **300**. FIG. **4** depicts a fleshy tissue site **10** for sensor attachment, such as a finger or thumb **400**. The tissue **10** has an epidermis **12**, a dermis **14**, subcutaneous and other soft tissue **16** and bone **18**.

FIG. **5** depicts a conventional pulse oximetry sensor **20** having a detector **22**, an emitter **24** and a tape **26** attached to the fleshy tissue **10**. Transmitted light **30** propagating from the emitter **24** to the detector **22** that results in a significant contribution to pulse oximetry measurements passes through and is absorbed by the pulsatile blood in the dermis **14**. A portion of the transmitted light **30** is scattered out of the epidermis **12** and reflected by the tape **26** back into the fleshy tissue **10**. The detector field-of-view (FOV) **40** is relatively wide and, as a result, the detector responds to transmitted light **30** that has propagated, at least in part, outside of the fleshy tissue **10**.

FIG. **6** depicts a cyanotic infant sensor **300** that is configured to limit variations in the mean pathlength ratio. In particular, the sensor **300** has a light absorbing tape inner surface **324** that reduces transmitted light reflection back into the tissue site **10**, as described with respect to FIGS. **3**A-B, above. Further, the detector **342** has a limited FOV **50** so as to reduce the detection of transmitted light that has propagated outside of the tissue site **10**, as described in detail with respect to FIGS. **7-9**, below.

FIGS. **8-9** illustrate cyanotic infant sensor embodiments having a limited detector field-of-view (FOV). FIGS. **7**A-B illustrate a conventional sensor **700** having a tape portion **760**, a detector window **762** and a detector **742** having a relatively wide FOV **701**. In particular, the window thickness does little to restrict the FOV. FIGS. **8**A-B illustrate one embodiment of a cyanotic infant sensor **300** having a material portion **360**, a detector window **362** and a detector **342** having a restricted FOV **801**. In particular, the material thickness **360** functions to define the FOV **801**. In one embodiment, the material thickness **360** comprises a flex circuit thickness and a base head tape thickness, as described with respect to FIG. **3**B, above. FIGS. **9**A-B illustrate another embodiment of a cyanotic infant sensor **900** having a material portion **960**, a detector window **962** and a detector **942** having a restricted FOV **901**. In particular, an O-ring **980** deposed around the window **962** defines the FOV **901**.

FIG. **10** depicts an exemplar calibration surface **1000** for a cyanotic infant sensor **300** (FIGS. **3**A-B) calculated along a DC response ratio axis **1001**, a ratio-of-ratios axis **1003** and a resulting oxygen saturation axis **1005**. Matching the

emitters and detectors, as described with respect to FIG. **3**A, above, allows for pathlength calibration. In particular, variations in the detector DC response ratio (RD_{dc}/IR_{dc}) are attributed to variations in the mean pathlength ratio (EQ. 3). As such, a calibration surface is determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation, as is done for a conventional calibration curve (FIG. **2**). A calculated DC response ratio **1001** in combination with a conventionally calculated ratio-of-ratios **1003** is then used to derive an oxygen saturation **1005** for the calibration surface **1000**.

A cyanotic infant sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A method for determining a physiological parameter, the method comprising:

receiving, from one or more detectors, one or more intensity signals responsive to light of a plurality of wavelengths attenuated by body tissue of a patient, said light emitted from a plurality of emitters, wherein said plurality of emitters and said one or more detectors are matched to reduce variations in a response of said one or more detectors that are not attributable to variations in a mean pathlength ratio of said light traveling through said body tissue between said plurality of emitters and said one or more detectors;

electronically retrieving mapping data including a relationship between DC response ratio data, ratio-of-ratios data, and oxygen saturation data;

electronically calculating a DC response ratio value responsive to said one or more intensity signals;

electronically calculating a ratio-of-ratios value responsive to said one or more intensity signals; and

electronically deriving an oxygen saturation measurement responsive to said mapping data.

2. The method of claim **1**, comprising electronically displaying the patient's oxygen saturation responsive to said oxygen saturation measurement.

3. The method according to claim **1**, wherein said calculating said DC response ratio comprises calculating said DC response ratio as a ratio of a detected incident intensity of the light at a first wavelength of said plurality of wavelengths to a detected incident intensity of the light at a second wavelength of said plurality of wavelengths.

4. The method according to claim **1**, further comprising emitting said light from said plurality of emitters and receiving said light at one or more detectors.

5. The method according to claim **1**, wherein a first subset of the plurality of emitters have been matched to transmit light at a first wavelength and a second subset of the plurality of emitters have been matched to transmit light at a second wavelength, wherein said matching of said emitters to said first and second wavelengths reduces variations in said response of said one more detectors not attributable to variations in said mean pathlength ratio of said light traveling through said body tissue between said plurality of emitters and said one or more detectors.

6. The method according to claim **1**, wherein an emitted DC intensity ratio of said plurality of emitters for at least one predetermined DC drive current has been matched to a first predetermined constant, and wherein said matching of said emitted DC intensity ratio to said first predetermined constant further reduces variations in said response of said one more detectors not attributable to variations in said mean pathlength ratio of said light.

7. The method according to claim **6**, further comprising receiving said light at one or more detectors and generating said intensity signals from said light received at said one or more detectors.

8. The method according to claim **7**, wherein a DC response ratio of said one or more detectors having a first wavelength response over a second wavelength response for at least one predetermined DC incident intensity has been matched to a second predetermined constant, and wherein said matching of said DC response ratio to said second predetermined constant further reduces variations in said response of said one more detectors not attributable to variations in said mean pathlength ratio of said light.

9. The method according to claim **1**, further comprising limiting a field-of-view of said one or more detectors so as to substantially limit said light received at said one or more detectors to portions of said light that propagate entirely through said body tissue.

10. A pulse oximeter comprising one or more processors configured to execute the method of claim **1**.

11. The pulse oximeter of claim **10**, further comprising the plurality of emitters configured to emit said light and the one or more detectors configured to detect said light.

12. The pulse oximeter of claim **10**, further comprising a memory, said memory storing said mapping data.

13. The pulse oximeter of claim **12**, wherein said memory comprises read only memory.

14. A pulse oximeter comprising:

a sensor configured to output one or more intensity signals responsive to light attenuated by body tissue of a patient wearing said sensor, said sensor comprising plurality of emitters and one or more detectors, wherein said plurality of emitters and said one or more detectors are matched to reduce variations in a response of said one or more detectors that are not attributable to variations in a mean pathlength ratio of said light traveling through said body tissue between said plurality of emitters and said one or more detectors;

a memory storing mapping data representing relationships between DC response data, ratio-of-ratios data, and oxygen saturation data; and

a processor responsive to said output signals to determine a DC response and a ratio; said processor configured to determine a measurement value responsive to said relationships stored in said memory.

15. The pulse oximeter of claim **14**, further comprising a patient monitor housing for housing said processor and said memory.

16. The pulse oximeter of claim **14**, further comprising a sensor housing for housing said memory.

17. The pulse oximeter of claim **14**, further comprising a display configured to display said measurement value.

18. The pulse oximeter of claim **14**, wherein:

a first subset of the plurality of emitters are matched to transmit light at a first wavelength and a second subset of the plurality of emitters are matched to transmit light at a second wavelength;

an emitted DC intensity ratio of said plurality of emitters for at least one predetermined DC drive current is matched to a first predetermined constant; and

a DC response ratio of said one or more detectors having a first wavelength response over a second wavelength

response for at least one predetermined DC incident intensity is matched to a second predetermined constant;

wherein said matching of said emitters to said first and second wavelengths, said matching of said emitted DC intensity ratio to said first predetermined constant, and said matching of said DC response ratio to said second predetermined constant reduces variations in a response of said one more detectors not attributable to variations in a mean pathlength ratio of said light traveling through said body tissue between said plurality of emitters and said one or more detectors.

19. The pulse oximeter of claim **14**, wherein said memory comprises read only memory.

20. A physiological sensor for outputting one or more intensity signals responsive to light attenuated by body tissue of a patient wearing, said sensor comprising:

a plurality of emitters having predetermined emitter operating characteristics, wherein a first subset of the plurality of emitters are matched to transmit light at a first wavelength and a second subset of the plurality of emitters are matched to transmit light at a second wavelength, and wherein an emitted DC intensity ratio of said plurality of emitters for at least one predetermined DC drive current is matched to a first predetermined constant; and

one or more detectors having predetermined detector operating characteristics, wherein a DC response ratio of said one or more detectors having a first wavelength response over a second wavelength response for at least one predetermined DC incident intensity has been matched to a second predetermined constant;

wherein matching of said emitters to said first and second wavelengths, said matching of said emitted DC intensity ratio to said first predetermined constant, and said matching of said DC response ratio to said second predetermined constant collectively reduce variations in a response of said one or more detectors that are not attributable to variations in a mean pathlength ratio of said light traveling through said body tissue between said one or more emitters and said one or more detectors.

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